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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,146	08/10/2001	Douglas J. Daniels	BSC-008DV	6909

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TESTA, HURWITZ & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/928,146

Applicant(s)

DANIELS ET AL.

Examiner

Eleni Mantis Mercader

Art Unit

3737

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al.'984 in view of Hiki et al.'630.

Regarding claims 36-48, 50-52, and 54-55, Chu et al.'984 teaches a method of imaging and performing an interventional procedure on tissue, comprising the steps of:

inserting a catheter having an ultrasound imaging device located at its distal end (see col. 1, lines 47-54) through a working channel of the endoscope (see col. 5, lines 8-10; describing introduction of the catheter through an endoscope; by definition an endoscope is inserting an instrument or a catheter through a lumen of a body of a living being (see for example according to Webster's definition (copyright 1984) an endoscope is an instrument for the examination of the interior of a canal or hollow viscus);

imaging a tissue structure located at a distal end of the catheter with the ultrasound imaging device and displaying the tissue structure in a manner that indicates the depth of penetration of the tissue structure into the body of the living being in order to perform interventional therapy on the tissue structure, the interventional therapy being performed in a manner responsive to the displayed depth of penetration of the tissue structure (see col. 6, lines 42-57 also see the embodiment of Figure 36).

Chu et al.'984 teach the use of a cutting element in combination with the ultrasonic imaging, engaging with an interventional device inserted through a working channel to perform therapy, while the tissue structure is being imaged by the ultrasound imaging device (see Figure 36). However, Chu et al.'984 do not expressly state that these working channels could be part of an endoscope, even though they do state that an endoscope could be utilized (col. 5, lines 8-10).

In the same field of endeavor, Hiki et al.'630 expressly teach the use of an endoscope having multi channels including a channel for insertion of the cutting instrument of choice such as forceps (see element 12 of Figure 2; and see col. 4, lines 38-54).

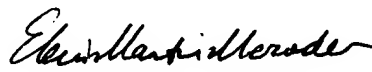
It would have been obvious to one skilled in the art at the time that the invention was made to have modified Chu et al.'984 by utilizing the ultrasonic transducer which is insertable into the channel for observation of the cutting procedure of choice in a separate channel of an endoscope as indicated by Figure 2 of Hiki et al.'630 as opposed to a separate portion of a catheter as indicated by Figure 36 of Chu et al.'984 which is usable with an endoscope, as an alternative functional equivalent resulting the same end result which an alternative channel for introduction of the cutting instrument for observation of the cutting procedure.

Regarding claims 49 and 53, Chu et al.'984 do not teach the use of an optical imager. In the same field of endeavor, Hiki et al.'630 teach the use of an optical imager in addition to the ultrasonic observation means in order to provide a more efficient and thorough image of the region as is well within the knowledge of skilled artisans.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM